K024337

JUL 0 3 2003

510(k) Summary of Safety and Effectiveness

Intended Use

The *GSA kit* is for the evaluation of human semen. The kit provides the user with a set of reagents used to evaluate semen quality by measuring four parameters, recommended by the World Health Organization (WHO), that are used to help determine whether infertility is caused by abnormalities of one or more of them. The parameters to be tested for include:

- Sperm count
- Sperm motility
- Sperm vitality
- White blood cell (WBC) count

The *GSA kit* is an *in vitro* diagnostic kit intended for use in a clinical laboratory test setting such as a test facility capable of providing laboratory assessment of male infertility, by skilled laboratory technicians, familiar with the handling of semen samples. This product does not contain biological materials of human origin.

The performance of the *GSA kit* was established by comparison to the manual method as recommended by the WHO.

The *GSA kit* involves specimen acquisition by ejaculation of semen by the patient for testing purposes. This assay presents no more of a safety hazard than the routine tests where semen samples are obtained from subjects.

Test Performance

The clinical performance of the *GSA kit* was evaluated via blind, multi-center, prospective clinical studies. The primary objective was to determine whether evaluation of sperm cells using the GSA kit is at least as accurate as the Routine Method. Another objective was to show that using the GSA kit provides more consistent results that are less dependent on the skills of an individual technician.

The study took place at two sites:

- IVF unit and outpatient clinic – Lin Center, Carmel Hospital, Israel.
- Baylor College of Medicine, Houston Medical Center, USA.

Each of the above sites has many years of experience performing semen analysis using the Routine Method.

A skilled laboratory technician evaluated each semen sample by the Routine Method and by a different skilled laboratory technician using the Flowcytometry method. The evaluation was based on the parameters recommended by the WHO (see below).

Sperm Count

Comparison of the GSA kit and the Routine Method showed that using the GSA kit with the Flowcytometer provides comparable accuracy and more precise results. The Flowcytometer allows counting of approximately 100 times more cells as compared to the light microscope and counting chamber.

The inter- and intra-technician experiments showed that in semen samples with approximately normal sperm count there is 91.6% agreement between the two methods while the reproducibility achieved by the Flowcytometry method is significantly higher.

Sperm Motility

Comparison of the GSA kit with the Routine Method showed that using the GSA kit provides comparable accuracy and more precise results. Again, because of the large amount of sperm cells that can be analyzed and the higher precision in cell count, the determination of the percentage of motile cells is statistically more reproducible using the GSA kit.
The inter- and intra- technician experiments showed that in semen samples characterized by approximately normal sperm count, there is close agreement (82.3%) between the two methods while the reproducibility achieved by the GSA kit is significantly higher.

Sperm Vitality

Comparison of the GSA kit with the Routine Method showed that using the GSA kit provides comparable accuracy and significantly more precise results.

The inter- and intra-technician experiments showed that in semen samples characterized by approximately normal sperm count, there is close agreement between the two methods while the reproducibility achieved by the GSA kit is significantly higher.

White Blood Cells (WBC)

Comparison of the GSA kit with the Routine Method showed that using the GSA kit provides comparable accuracy and more precise results.

Intra-Technician Precision

In an attempt to determine and compare the intra-technician precision of the two methods, five semen samples were repeatedly tested by both conventional (light microscope and counting chamber) analysis and Flowcytometry analysis according to the WHO manual. For each analysis method the same technician repeatedly evaluated the

semen samples in order to evaluate the intra-technician variability obtained by each methodology. The results show that by using the GSA kit the typical intra-technician standard deviation for each parameter is smaller then by using the Routine Method indicating a high intra-technician precision for Flowcytometry assay.

Inter-Technician Precision

To compare the inter-technician precision of the two methods six semen samples were tested by both conventional analysis and Flowcytometry analysis according to the WHO manual method. For each analysis method three technicians evaluated all semen samples and the results obtained for each sample by each technician were compared in order to evaluate the inter-technician variability obtained by each methodology. The results show that by using the GSA kit the typical inter-technician standard deviation for each parameter is significantly smaller then by using the Routine Method indicating a high inter-technician precision for Flowcytometry assay.

Interfering Substances

The following table summarizes data obtained using human semen samples characterized by certain abnormalities.

Interfering Substance	**Amount**	**Result**
High level of WBC	$\geq 4 \times 10^7$ /ml	May cause high staining background and by this false WBC count result. A new sample must be obtained after the infection is over.
Fungi infection	Visible cloudiness	May cause auto-fluorescence which can result in erroneous results. Thus, contaminated semen samples should not be tested.
Extremely viscous semen sample.	-	In rare cases dilution of the sample is practically impossible and dilution treatment using Bromolin may be required.

Product Stability

The stability of the kit was tested in real time as the components were stored refrigerated and the performance tested periodically. The shelf life of the kit has been determined to be 6 months at the specified storage conditions.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

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Silver Spring, MD 20993

DEC 21 2012

Devices & Diagnostics Consulting Group, Inc.
c/o Mr. Thomas M. Tsakeris
President
16809 Briardale Road
Rockville, Maryland 20855

Re: k024337
Trade/Device Name: BioShaf Limited General Semen Analysis (GSA) Kit
Regulation Number: 21 CFR § 864.5220
Regulation Name: Automated differential cell counter
Regulatory Class: Class II
Product Code: GKZ
Date: April 28, 2003
Received: April 28, 2003

Dear Mr. Tsakeris:

This letter corrects our substantially equivalent letter of July 3, 2003.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Maria M. Chan

Maria M. Chan, Ph.D.
Director
Division of Immunology and Hematology Devices
Office of *In Vitro* Diagnostics and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number: K024337

Device Name: General Semen Analysis (GSA) Kit

Indications for Use:

The **GSA kit** is for the evaluation of human semen. The kit provides the user with a set of reagents used to evaluate semen quality by measuring four (4) parameters recommended by the World Health Organization (WHO) that are used to determine whether infertility is caused by abnormalities of one or more of them. The parameters include:

- Sperm count
- Sperm motility
- Sperm vitality
- White blood cell (WBC) count

In most fertility test laboratories these parameters are manually evaluated on a routine basis using a light microscope and a counting chamber. The performance characteristics of the **GSA kit** is based on a comparison between the **GSA kit** and the routine manual method performed according to the latest edition of the Manual for the Examination of Human Semen and Sperm published by the WHO.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Evaluation and Safety (OIVDES)

Professional use: ✓

Prescription Use: _____
(Per 21 CFR 801.109)

OR

Over-the-counter Use: _____
(Optional Format 1-2-96)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K024337